REMARKS

I. STATUS OF THE APPLICATION:

Claims 1-8, 11-25 and 28-55 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S.P.A. Pub. No. US2003/0208454 ("Rienhoff et al.") in view of U.S.P.A. Pub. No. US2003/0110058 ("Fagan et al."), and further in view of U.S.P.A. Pub. No. US2003/0082865 ("Bianco").

Each of the independent claims 1, 18, 34, 35, 36, 37, 47 and 48 has been amended. Claims 5, 6, 7, 22 and 24 have been canceled. Claims 1-4, 8, 11-21, 23, 25 and 28-55 are currently pending.

II. CLAIM REJECTIONS UNDER 35 U.S.C. 103:

As mentioned, claims 1-8, 11-25 and 28-55 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Rienhoff et al. in view of Fagan et al., and further in view of Bianco. As explained below, in light of the amendments, Applicants believe that the Application is now in condition for allowance.

A. None Of The Cited References Teach "Event Data For Tracking Events Associated With Medical Treatment Of Candidate Subjects" For A "Clinical Data Study"

Each of the independent claims 1, 18, 34, 35, 36, 37, 47 and 48 has been amended to recite "event data for tracking events associated with medical treatment of the candidate subjects" wherein the candidates are "subjects for a clinical data study." Support for these amendments is found in the Specification as originally filed. *See* Specification at ¶¶ 184-186, 190 and 233-236.

As the Examiner notes correctly, Rienhoff et al. and Fagan et al. do not teach "event data," and thus these references certainly do not teach the more specific recitation of "event data for tracking events associated with medical treatment of the candidate subjects" for a "clinical data study." *See* Office Action at p. 4, last paragraph. However, the Examiner points out that Bianco teaches a "patient medical event." *See* Office Action at pp. 4-5 citing Bianco at ¶ 78.

While Bianco teaches a "patient medical event," it does not teach use and access of "event data for tracking events associated with medical treatment of the candidate subjects" of a "clinical data study." Bianco does not even contemplate a "clinical data study." Rather, Bianco pertains to a system and method "*for guiding a patient through a medical event by educating and preparing the patient for the medical event and post-event recovery.*" Bianco at ¶ 78. The use of "event data" recited in the independent claims of the present application (*i.e.*, "for tracking events associated with medical treatment of ... subjects" of a "clinical data study") is very different from that described in Bianco. For example, the Bianco reference does not even contemplate a clinical data study. Nor does Bianco teach anything related to the purpose of the present invention, which is to "provide geographically disparate medical professionals with specialized views of patient-related data." *See* Specification at ¶ 2. It is clear that Bianco does not teach use and access of "event data for tracking events associated with medical treatment of the candidate subjects" of a "clinical data study" as recited in the amended independent claims.

Even assuming that Bianco suggested "event data for tracking events associated with medical treatment of the candidate subjects" of a "clinical data study," which it does not, a person of ordinary skill in the art would not have been motivated to combine the teachings of Bianco with the teaching of Fagan et al. and Rienhoff et al. because these references contemplate different problems, different objectives, and different advantages. Bianco teaches a "system for guiding a patient along a treatment pathway." *See, e.g.*, Bianco, Abstract. Thus, Bianco pertains to the field of educating and guiding medical patients. In contrast, Fagan et al. and Rienhoff et al. pertain to the field of storing and sharing biomedical information. The field of educating and guiding medical patients is disparate from the field of storing biomedical information. Because Bianco is not in the same field as Fagan et al. and Rienhoff et al., it is difficult to understand why a person of person of ordinary skill in the art would have been motivated to combine the teachings of Bianco with the teaching of Fagan et al. and Rienhoff et al. to arrive at the claimed invention.

Because none of the cited references teaches "event data for tracking events

associated with medical treatment of the candidate subjects" wherein the candidates are "subjects for a clinical data study," amended independent claims 1, 18, 34, 35, 36, 37, 47 and 48 are patentable over the cited references. Claims 2-4, 8, 11-17 and 39 depend from patentable claim 1, rendering them patentable also. Claims 19-21, 23, 25, 28-33, 40, 45 and 46 depend from patentable claim 18, rendering them patentable as well. Claims 41-43 depend from patentable claims 34-36 respectively, rendering them patentable also. Claim 38 depends from patentable claim 37, rendering it patentable as well. Claims 49-55 depend from patentable claim 48, rendering them patentable also.

B. None Of The Cited References Teach The "Roles Defining Data Access Rights" As Recited In Each Of The Amended Independent Claims

Each of the independent claims 1, 18, 34, 35, 36, 37, 47 and 48 has been amended to include the limitation "roles" defining data access rights associated with the users "***wherein the roles include a data monitor role entitling a user to review specified data, an enroller role entitling a user to enroll candidate subjects in a study, a data editor role entitling a user to add and edit data, a data study administrator role entitling a user to assign roles to users, and a system administrator role entitling a user to manager user access to the system for specified roles.***" *See* above amendments. Support for these amendments is found in the Specification as originally filed. *See, e.g.*, Specification at ¶¶ 87-99 and 138-180.

Portions of the above-described added limitations were previously presented in dependent claims 6, 7 and 24, which have been cancelled. *See, e.g.*, canceled claim 7 (reciting "wherein the role is selected from the group of data monitor, enroller, data editor, study administrator, system administrator, and user administrator.") The Examiner stated that the limitations of canceled claims 6, 7 and 24 are found in Rienhoff et al. *See* Office Action at ¶¶ 11-12 and 36 citing Rienhoff et al. at ¶ 41. This portion of Rienhoff et al. states:

> [0041] An important technique for developing trust is to provide users with control and privacy rights over information they submit to the web site, and to make those rights known to the user. Trust is increased or maintained when policies of the web site take the

> patient's position in legal, and ethical issues. For example, users may be given strict control in determining who may access information they have submitted, which of the information may be accessed, and in what form the information is provided to others. For example, in some embodiments, user information may be provided to others in a form that is aggregated among many users and which does not identify the individual users. Also, users may be given the option, at any time, of having their information deleted from any databases as well as having any of their biological samples destroyed. Moreover, phenotypic and genotypic data submitted by users should be highly secured. Thus, in some embodiments, one or more of the database or databases that archive such information are not directly coupled to the Internet. Policies of the web site should be clearly posted and easily readable by lay persons.

Rienhoff et al. at ¶ 41.

While the above-cited portion of Rienhoff et al. pertains generally to user access rights, it does not contemplate all of the different roles entitling users to different types of access rights as recited in each of the amended independent claims 1, 18, 34, 35, 36, 37, 47 and 48. The various roles and access rights cited the amended independent claims facilitate the clinical research data management system and method of the present invention, which provides geographically disparate medical professionals with specialized views of patient-related data. *See, e.g.*, Specification at ¶¶ 2, 4, 10 and 16-19. These technical advantages are not provided by the teachings of the prior art references.

In conclusion, none of the cited references teach the limitation "roles" defining data access rights associated with the users "wherein the roles include a data monitor role entitling a user to review specified data, an enroller role entitling a user to enroll candidate subjects in a study, a data editor role entitling a user to add and edit data, a data study administrator role entitling a user to assign roles to users, and a system administrator role entitling a user to manager user access to the system for specified roles" as recited in each of the amended independent claims 1, 18, 35, 36, 37, 47 and 48. Because none of the cited references teach these limitations, amended independent claims 1, 18, 35, 36, 37, 47 and 48 are patentable over the cited references.

Claims 2-4, 8, 11-17 and 39 depend from patentable claim 1, rendering them

patentable also. Claims 19-21, 23, 25, 28-33, 40, 45 and 46 depend from patentable claim 18, rendering them patentable as well. Claims 41-43 depend from patentable claims 34-36 respectively, rendering them patentable also. Claim 38 depends from patentable claim 37, rendering it patentable as well. Claims 49-55 depend from patentable claim 48, rendering them patentable also.

C. None Of The Cited References Teach "Event Data Includes Scheduled Events, Unscheduled Events, or Both" As Recited In Dependent Claims 2, 19 and 46

Each of claims 2, 19 and 46 recite "wherein the event data includes scheduled events, unscheduled events, or both." As explained above, each of the independent claims has been amended to recite "events associated with medical treatment of the candidate subjects." Thus, in light of the amendments to the independent claims, the "event data" recited in dependent claims 2, 19 and 46 now clearly pertains to "medical treatment" of candidate subjects. In contrast, the events pointed out by the Examiner in the teachings of Rienhoff et al. pertain to "interviews or discussions." *See* Office Action at ¶ 6 citing Rienhoff et al. at ¶ 44. None of the cited references teach data representing "events associated with medical treatment" wherein the "event data includes scheduled events, unscheduled events, or both." Therefore, claims 2, 19 and 46 are patentable over the cited references.

D. None Of The Cited References Teach "Data Access Rights Granted At A Dataset Definition Level Or Data Item Definition Level Or Both" As Recited In Claims 8, 25, 50 And 51

Each of claims 8, 25, 50 and 51 recites the limitation "wherein the role defines data access rights granted at a dataset definition level, data item definition level, or both." None of the cited references teach this limitation, including the portion of Rienhoff et al. relied upon by the Examiner. *See* Office Action at ¶ 12 citing Rienhoff et al. at ¶ 41.

III. CONCLUSION REGARDING CLAIM REJECTIONS UNDER 35 U.S.C. 103:

Although the foregoing examples are not exhaustive, it is clear from these examples that the cited references do not support a prima facie case of obviousness of pending claims 1-4, 8, 11-21, 23, 25 and 28-55 (claims 5, 6, 7, 22 and 24 are cancelled).

Because they are neither taught nor suggested by the cited references, claims 1-4, 8, 11-21, 23, 25 and 28-55 are allowable over the cited references. Accordingly, Applicants respectfully request reconsideration and withdrawal of the claim rejections.

Respectfully submitted,

DECHERT LLP

Dated: January 30, 2006

Justin Boyce
Reg. No. 40,920

DECHERT LLP
Customer No. 37509
P.O. Box 10004
Palo Alto, CA 94303-0961
Tel: 650. 813.4800
Fax: 650.813.4848

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being forwarded via facsimile to Examiner Sadiyanarayan Pannala in Group No. 2164 at facsimile number 571.273.8300 located at Mail Stop Amendment Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313-1450, on

Date: January 30, 2006

Yolette Yumakle-Owen